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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,035	04/01/2004	Stephen Bennett Elliott		6285

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EXAMINER
MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/814,035

Applicant(s)

ELLIOTT, STEPHEN BENNETT

Examiner

Deborah Malamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 13 and 17-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 13 and 17-35 is/are rejected.
- 7) ☒ Claim(s) 36-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 2-10, 12 and 14-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 December 2006.
2. Claims 2-10, 12 and 14-16 are cancelled; new claims 17-38 are added; claims 1, 11, 13 and 17-38 are pending.

Claim Objections

3. Claim 36 is objected to because of the following informalities: the phrase (line 2) "and, in being adapted to control the reciprocating regulator to..." presents an improper antecedent basis, since the limitation reciprocating regulator has just been introduced in this claim. The examiner suggests changing lines 2-3 of the claim to read "comprises a reciprocating regulator, wherein the electrically-controlled regulator is configured to control the reciprocating regulator to..."
4. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 11, 13, 17 and 21-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaschillo et al (U.S. 5,997,482) in view of Krebs (U.S. 2002/0185126). Vaschillo discloses (col. 3, lines 25-37) a method of individually determining an optimal relationship between respiratory and heartbeat frequencies, including the steps of "a) continuously measuring heartbeat and respiratory rates of a subject and converting the rates into respective heart sinusoidal and respiratory electrical signals; b) selecting a sinusoidal reference signal with a first frequency lying in a frequency range of 0.01 to 0.14 Hz; c) simultaneously displaying the reference and heart signals to the patient[; and] d) instructing the patient to modify the respiratory rate according to the sinusoidal reference signal." The examiner considers this to be monitoring a heartbeat rate of the care recipient to determine a heart rate variability cycle of the care recipient; providing an indicator to the care recipient indicative of the periods of increasing and decreasing heartbeat rate; and instructing the care recipient to synchronize inhalation and exhalation phases of a breathing cycle of the care recipient with the periods of increasing and decreasing heartbeat rate, respectively.

7. Vaschillo discloses the claimed invention except for dispensing a therapeutic gas to the care recipient during the inhalation phase of the breathing cycle. Krebs however discloses (par. 0014) a method for dispensing gas to a patient by metering one or more gases, advantageously taking place only during inspiration phases, wherein no gas metering takes place during expiration. The start and/or end of inspiration or the start "is detected by a control unit on the basis of sensor measured values." The gas

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metering may be controlled (par. 0023) "on the basis of a response curve previously determined on the patient. To determine the response curve, a sensor is used to measure a body parameter of the patient (e.g. oxygen saturation in the peripheral blood and/or heart rate, determined by means of pulse-oxymeter) as a function of the metered volume of gas or gas concentration, and the temporal gas demand required to establish a uniform body condition is determined."

8. Krebs and Vaschillo both disclose methods of monitoring heart rate and inhalation and exhalation phases of a patient in order to treat a respiratory condition. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vaschillo's respiratory cycle-heart rate synchronization method with Krebs' gas metering in order to provide an immediate therapy to the patient that is simultaneously undergoing a self-controlled breathing normalization process.

9. Regarding claims 25-26, Vaschillo discloses (col. 2, lines 45-60) an assembly for performing the method comprising "first means for registering a subjects's [sic] current respiration rate and for converting the latter into a first electrical signal; second means for registering a current heartbeat of the subject and for converting the latter into a second electrical signal; monitor means operatively connected with the second means for displaying the second signal and a reference signal juxtaposed with the second signal and having a frequency arbitrarily selected from a predetermined frequency range; processing means for spectrally analyzing the first and second electrical signals and for generating a resulting signal corresponding to a phase shift therebetween." The examiner considers this to be a care recipient indicator, a heartbeat detector, and a

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heart rate variability monitor adapted to perform the claimed functions. Krebs discloses, (par. 0035) "Control equipment for gas metering can advantageously be controlled electrically." Control equipment used is, for example comprised of "automatically adjustable pressure regulators (e.g. adjustable by means of stepper motor or electric motor) or control valves for the direct, in particular automatic, adjustment of the gas pressure." The examiner considers this to be an electrically controlled regulator adapted to perform the claimed functions.

10. Regarding claim 11, Vaschillo discloses (col. 5, lines 65-67) registering a current heartbeat and processing this data such that (col. 6, lines 33-44) the amplitude of the testing sinusoidal signal corresponds to the variation of heart rate.

11. Regarding claims 13 and 27, the examiner considers Vaschillo's Figure 3A to illustrate a method in which the inhalation phases of the breathing cycle are synchronized with the periods of increasing and decreasing heartbeat. This method is implemented (col. 3, lines 20-24) by controlling the resonance frequency to provide a zero (minimal) phase shift between heart and breath oscillations.

12. Regarding claim 17 and 28, Krebs discloses, (par. 0035) "Control equipment for gas metering can advantageously be controlled electrically." Control equipment used is, for example comprised of "automatically adjustable pressure regulators (e.g. adjustable by means of stepper motor or electric motor) or control valves for the direct, in particular automatic, adjustment of the gas pressure." The examiner considers this to be automatically controlling an electrically controlled regulator. Krebs' gas metering system is (par. 0008) inspiration-synchronized.

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13. Regarding claims 21-23 and 32-34, Krebs discloses, (par. 0061) "The trigger of the start of the inspiration phase and hence the beginning of opening of the solenoid valve can be triggered by the low-pressure sensor (P2). The duration of opening and therefore the volume to be administered is displayed or adjusted by means of a volume assigned to a potentiometer on the control unit (6) (or by input/display of a more highly electronicized system, such as for example microprocessor/controller)." The examiner considers this to be providing an indicator to a care practitioner indicative of the dispensing of the therapeutic gas to the care recipient during the inhalation phase of the breathing cycle. Since Vaschillo in view of Krebs provides a system with patient self-control of therapy, the examiner considers an indication provided to the care recipient to also be an indication provided to the care recipient.

14. Regarding claims 24 and 35, and further regarding claims 22-23 and 33-34, Vaschillo discloses (col. 6, lines 45-52) "FIG. 2 shows diagrammatically a practical implementation of the above described principle method shown in FIG. 1. While display means (7) can be any means for instructing the subject to follow the chosen reference signal, the most convenient means has been found to be the visual one demonstrating two sinusoids of the heart rate signal and the modified reference signal one under the other." The examiner considers this to be providing a visual indicator to the care recipient. Since the gas is dispensed during the inhalation phase of the patient's respiratory cycle, the examiner considers a device that displays the inhalation phase of a patient to also display the dispensing of the therapeutic gas to the care recipient. Furthermore, the examiner considers the sinusoidal inspiration waveforms displayed in

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Vaschillo's Figure 2 to comprise a visual indicator that varies in intensity when dispensing the therapeutic gas at a peak flow rate.

15. Regarding claims 29-31, the examiner considers the system of Vaschillo in view of Krebs to be adapted to perform the claimed functions. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

16. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaschillo et al (U.S. 5,997,482) in view of Krebs (U.S. 2002/0185126) and in further view of Lutchen et al (U.S. 6,435,182). Vaschillo in view of Krebs discloses the claimed invention except for the specific open or closed position timing of the electronically controlled regulator. Lutchen however discloses (col. 8, lines 39-49; Figures 2A-2B) an enhanced ventilator waveform (EVW) device that performs the steps of "sustaining mechanical ventilation with the delivery of an appropriate volume of fresh gas to the patient using an inspiratory flow pattern (32) identical to the OVW shown in FIG. 2A; and 2) allowing the patient to passively exhale to the atmosphere (34). As with the OVW, a preferred embodiment of this particular EVW contains two distinct physiological breaths per complete cycle." The examiner considers this to be a method of providing a peak therapeutic gas flow at mid-inhalation during the inhalation phase of the breathing cycle. Lutchen further discloses, (col. 15, lines 22-41; Figure 4) "During inspiration, the net forward motion of the piston (48) generated sufficient positive pressure in the

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cylinder to open the outlet leaflet valve (54) and keep the intake leaflet valve (52) closed. Precisely at end inspiration (when the piston has reached its maximal forward displacement), the exhalation valve (56) is triggered opened by an additional D/A channel (40A) (for example, D/A-0). The diaphragm position of this exhalation valve is controlled pneumatically. Thus, the additional D/A channel toggles two 3-way solenoid valves (S1, S2) via a relay driver circuit (58) to control the presentation of either 12 PSI compressed air (60) or 20" Hg suction (62) to the valve from a 1/45 HP compressor (64). The back-pressure generated by the passive exhalation of the patient closes the outlet leaflet valve, while the simultaneous backstroke of the piston generates sufficient negative pressure to open the intake leaflet and bring fresh gas from the atmosphere into the cylinder. PEEP is provided by spring-loaded valve (66) connected to the outlet of the exhalation valve." The examiner considers this to be opening the electrically controlled regulator to provide a peak therapeutic gas flow at mid-inhalation; beginning to close the electrically controlled regulator after mid-inhalation such that the electrically controlled regulator is in a fully-closed position prior to when the exhalation phase of the breathing cycle begins; and maintaining the electrically controlled regulator in the fully-closed position during the exhalation phase of the breathing cycle.

Allowable Subject Matter

17. Claims 36-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

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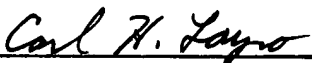
the base claim and any intervening claims, as well as to correct for the claim objections indicated above.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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